

DEC 20 2002

K023870
page 1 of 1
000066

Summary of Safety and Effectiveness

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

General Information

Submitter: Boston Scientific Corporation
780 Brookside Drive
Spencer, IN 47460

Contact Person: Nicholas Condakes

General Provisions

Trade Name: Flexima Biliary Catheter

Classification Name: Biliary Catheter and Accessories

Name of Predicate Devices

Flexima Biliary Catheter

Classification

Class II

Performance Standards

Performance Standards have not been established by FDA under Section 514 of the Food, Drug and Cosmetic Act

Intended Use and Device Description

The Flexima Biliary Catheter is designed for external and internal percutaneous drainage of the biliary system. The major components of the Flexima Biliary Catheter are the drainage catheter, metal stiffening cannula, flexible stiffening cannula and luer cap.

Summary of Substantial Equivalence

The Flexima Biliary Catheters have been tested and compared to the predicate device. All data gathered demonstrate this device as substantially equivalent. No new issues of safety or efficacy have been raised.



DEC 20 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Nicholas Condakes
Regulatory Affairs Specialist II
Boston Scientific Medi-Tech®
Boston Scientific Corporation
One Boston Scientific Place
NATICK MA 01760-1537

Re: K023870
Trade/Device Name: Flexima™ Biliary Drainage
Catheter
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: November 19, 2002
Received: November 20, 2002

Dear Mr. Condakes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Special 510(k)
Flexima™ Biliary Catheter
Boston Scientific Corporation

K023870

000063

Indications For Use

510(k)
Number
(if known)

Device Name: Flexima™ Biliary Catheter

Indications for Use The Flexima Biliary Catheter is designed for external and internal percutaneous drainage of the biliary system.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____
(Optional Format 1-2-96)

Confidential
Boston Scientific Corporation

(Division Sign Off)

Division of Biologics Control, Administrative

and Compliance Division

510(k) Number

K023870